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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,570	02/05/2002	Carl A. Schu	P-9201.02	5843
27581	7590	05/16/2005		
EXAMINER				
EVANISKO, GEORGE ROBERT				
ART UNIT		PAPER NUMBER		
3762				

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,570	SCHU ET AL.	
	Examiner George R Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 March 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 25-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the election of species in the reply filed on 3/22/05 is acknowledged. The traversal is on the ground(s) that there is no undue burden imposed on the Examiner to examine the subject application as originally filed. This is not found persuasive because there is an undue burden since each embodiment contains a limitation that is not found in the other embodiment. Each limitation in a claim needs to be evaluated separately from a different limitation in another claim and therefore different searches and consideration are needed for different limitations.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected embodiment, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/22/05.

Claim Rejections - 35 USC § 112

Claims 25-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is the therapy delivery means operating "independently from said sensor and said signal processor", in combination with the other elements in the claim. The original specification contained no language or drawings stating or showing the therapy delivery means operating "independently"

from the sensor and signal processor. The original specification shows the exact opposite, as seen in figure 1 showing the sensors, 108, being connected through a two way arrow to the therapy delivery system, 106. In addition, the specification states that the therapy means is triggered by sensor signals, as seen on page 9, lines 10-15, page 10, lines 26-28, page 12, lines 3-5, page 20, lines 8-10, page 21, lines 12-14, page 25, lines 24-29, etc. and therefore the therapy means does not operate independently of the sensor and signal processor.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25, “independently” is vague since the scope and bounds of “independently” can not be determined. Does this mean there is no direct connection, no connection through another element, or no connection at all of the therapy means to the sensor and processor? In addition, does this mean the therapy means can not be triggered by a sensed or processed signal?

In claim 31, the claim is incomplete for omitting structural cooperative relationship between elements since the telemetry circuit is not connected to any other element in the claim.

In claim 32, the claim is incomplete for omitting an element to sense “cardiac” signals.

In claim 33, “the physiological status” lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25, 29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaser (4202341). Blaser discloses the claimed invention having a cardiac sense electrode (the claimed physiological sensor), a signal processor of self timed logic elements in a chain to process the signal, elements 2, 3, and 4, an operating system of logic circuits to generate a therapy trigger signal, elements 5 and 6, and therapy delivery means, elements 13 and 14 operating "independently" from the sensor and signal processor, except for the operating system being at least one integrated circuit. In addition, for claim 34, the system of Blaser is capable of meeting the functional use recitations of the processed signal relating to one of ischemia, arrhythmia, or a change in cardiac output since his system processes all cardiac signals and is used for irregular heart rhythms (arrhythmia). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacer system as taught by Blaser, with the operating system being at least one integrated circuit since it was known in

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the art that pacemakers have circuits and operating systems be at least one integrated circuit to reduce power consumption, size, and capacitance.

Claims 26, 27, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaser. Blaser discloses the claimed invention except for the sensor being electrodes, an activity sensor, or a blood pressure (or intra cardiac pressure), temperature, pH, or gas concentration sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacer system as taught by Blaser, with a sensor being electrodes, an activity sensor, or a blood pressure (or intra cardiac pressure), temperature, pH, or gas concentration sensor since it was known in the art that pacer systems use a sensor being electrodes to provide a bipolar, localized signal from the particular organ so as not to receive interference from other signals in the body and since it was known in the art that pacer systems use an activity sensor or a blood pressure, temperature, pH, or gas concentration sensor to provide an alternate conventional sensor that senses the heart beating, a sensor that can be located in a different part of the body, and/or a signal to the pacer system to allow the system to determine when cardiac therapy is needed.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaser.

Blaser discloses the claimed invention except for the system including a telemetry circuit for communication with a remote circuit, a memory activation means for causing storage of a temporal portion of the cardiac and physiological signals, and a memory for recording a temporal portion of the signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable system as taught by Blaser, with a telemetry circuit for communication with a remote circuit, a memory activation means for

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causing storage of a temporal portion of the cardiac and physiological signals, and a memory for recording a temporal portion of the signal since it was known in the art that implantable systems use a telemetry circuit for communication with a remote circuit to allow a physician to look at the cardiac data and adjust the therapy; a memory activation means for causing storage of a temporal portion of the cardiac and physiological signals to allow the patient to record cardiac and physiological signals when the patient thinks he is experiencing an arrhythmia so a doctor can look at the data; and a memory for recording a temporal portion of the signal to allow the data to be evaluated at a later date by a physician.

Response to Arguments

Applicant's arguments filed 3/22/05 have been fully considered but they are not persuasive. The argument that Blaser is devoid of any mention or use of the terms sensor or sense is not persuasive since Blaser senses the cardiac output and since the applicant argues that Blaser describes only traditional cardiac pacing and sensing. The argument that there is no motivation to modify the teaching of Blaser is not persuasive since in each rejection the examiner provided motivation, such as "since it was known in the art that pacemakers have circuits and operating systems be at least one integrated circuit to reduce power consumption, size, and capacitance" and "since it was known in the art that pacer systems use a sensor being electrodes to provide a bipolar, localized signal from the particular organ so as not to receive interference from other signals in the body". The arguments that the record consists exclusively of conclusory statements which are not evidence and the examiner has failed to present evidence to support his rejection are not persuasive since the record contains numerous documents to show

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the elements recited (IC circuitry, electrodes, activity sensors, etc) in the 103 rejections are well known in the art. The record contains several cited references in the specification and IDS, such as 5916237, 4561442, 4515159 (IC operating system) and 5388578 and 5154170 (bipolar electrodes and activity sensor), in addition to the applicants own Background section, which show the elements to be well known in the art. Finally, it is noted that the applicants have not stated or argued that those elements in the 103 rejection are not well known in the art and therefore have not addressed whether those elements are obvious or not.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762

5/12/5

GRE
May 12, 2005